



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

MAR 11 2005

Ms. Lisa Ni.  
Product Development Manager  
Tianshi Health Products, Inc.  
917 134<sup>th</sup> Street SW  
Suite A-8  
Everett, Washington 98204

Dear Ms. Ni:

This is in response to your letter of January 21, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that you are making the following claim, among others, for the product Tiens Berry Essentials Plus:

[S]upport the immune system as it battles allergies...."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases such as allergies. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

97S 0133 LET 816

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Please contact us if you require further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written in a cursive style.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Seattle District Compliance, HFR-PA340



TIENSHI HEALTH PRODUCTS, INC.

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Fax 425-741-8728  
info@tiensna.com  
www.tiensna.com

January 21, 2005

Dr. Elizabeth Yetley  
Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, D.C. 20204

RE: Notification of Product Claims

Dear Dr. Yetley:

This letter serves as a notification of the nutritional support label statements being made by Tianshi Health Products, Inc., located at 728 - 134<sup>th</sup> Street SW, Suite #222, Everett, WA 98204; in connection with the marketing of its line of dietary supplements. A list of the products and their respective nutritional support statements are listed in the attached Exhibit "A".

Tianshi Health Products, Inc. certifies that the information contained in this notice is complete and accurate, and that the company maintains documentation to substantiate that its product claims are truthful and not misleading.

If you have any questions, please feel free to contact the undersigned.

Sincerely,

Lisa Ni  
Product Development Manager  
Tianshi Health Products, Inc.

90895

## Exhibit A

## 1. Product: TiensBloc

**A dietary supplement containing:**

- a. White kidney bean extract (*Phaseolus Vulgaris*)
- b. Cactus extract (*Opuntia Ficus Indica*)

### Statements of Nutritional Support:

- a. Free from toxins
  - b. Can reduce digestion of about 85% of starch and 10-21 grams of fat per serving.
- Helps block excessive “bad fats” and unwanted carbohydrates/starches.

## 2. Product: Tiens- NutraCleanse

**A dietary supplement containing:**

- NutraFlora (Fructo-oligosaccharides)
- Cassia Acutifolia (Cassia Senna)
- Glucomannan

### Statements of Nutritional Support:

- a. helps in better digestion and weight control\*
- b. this formula contains Glucomannan, a water-soluble dietary fiber that can help reduce the elevation of blood sugar levels that is typical after a meal. \*\*
- c. Fructo-oligosaccharides improves the balance of friendly bacteria, improving regularity in the colon. \*\*\*

### 3. Product: Tiens Chitosan Capsules

### A dietary supplement containing: Chitosan powder

**Statement of Nutrition Support: None.**

#### 4. Product: Tiens Berry Essentials Plus

**A dietary supplement containing:**

Vitamin A (from Beta Carotene, Wolfberry)

Vitamin B12
Vitamin B5 (as Pantothenic Acid)
Wolfberry Concentrate
Tianshi Oxyberry concentrate blend (bilberry, plum, cranberry, blueberry, cherry, and grape)
White Tea Extract (90% polyphenol)
Astragalus Extract
Licorice Extract
Bioflavonoid Complex (Citrus, Grapefruit)
Quercetin
Citrus Aurantium
Aloe Vera Gel Extract
<b>Tianshi Herbal Blend:</b>
Reishi (Ling Zhi)
White Atractylodes (Bai Zhu)
Siler (Fang Feng)
Wild Ginger (Xixin)
Schizonepeta (Jing Jie)
Wild Yam (Shen Yao)
Coix (Yi Yi Ren)
Cordycep
Mentha (Bohe)
Platycodon (Jie Geng)
Codonopsis (Dang Shen)

#### Statements of Nutrition Support:

- a. Wolfberry has been found to support the immune system as it battles allergies, supports healthy energy levels, and aids in keen eyesight and kidney function.
- b. Wolfberry has the best source of Polysaccharides on the nutritional market today. Polysaccharides have been espoused as having a positive effect on T-Cell production.
- c. As an anti-oxidant, "Tiens Berry Essentials +" has an ORAC value of over 2,000 which makes it one of the best anti-oxidants on the market today.